PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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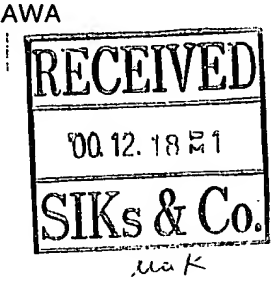

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	14.12.2000
Applicant's or agent's file reference: A01018M	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP00/00355	25/01/2000	25/01/1999

International Patent Classification (IPC) or both national classification and IPC

G06F19/00

Applicant

INSTITUTE OF MEDICINAL MOLECULAR DESIGN et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain document cited
VII	☒	Certain defects in the international application
VIII	☒	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 25/05/2001.

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I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

Description, pages:

1-39 as originally filed

Claims, No.:

1-16 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 1,12,13,

because:

☒ the said international application, or the said claims Nos. 1,12,13 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-5,7-9,11,14-16
Inventive step (IS)	Claims	6,10
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claim 12 defines a data record on a media including at least
   - its identifier;
   - a gap information;
   - identifiers of sequences in a sequence information.

   Such a data record merely comprises data encoding cognitive content in a standard manner. The three elements of the record cannot be regarded as functional data defined in terms which inherently comprise the technical features of the system in which the carrier is operative.
   Claim 12 therefore relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(v) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability of the subject-matter of claim 12 and dependent claim 13 (Article 34(4)(a)(i) PCT).

1.1 Claim 1 correspondingly defines a description method which separates an alignment information into a sequence information and a gap information.
This is considered to represent a pure abstract idea without any technical context, therefore the subject-matter defined in claim 1 also falls under the list of items set out in Rule 67.1 PCT for which no preliminary examination shall be carried out.

Re Item V
Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:

   D1: Stoesser G., Tuli M.A., Lopez R. and Sterk (1999) The EMBL Nucleotide Sequence Database. *Nucleic Acids Res.*, **27**, 18-24
   D2: Thompson J., Higgins D., Gibson J. (1994) CLUSTAL W: improving the

sensitivity of progressive multiple sequence alignment through sequence weighting, position-specific gap penalties and weight matrix choice. *Nucleic Acids Res.*, **24,** 4673-4680

2.1 The documents D1 and D2 were not cited in the international search report. A copy of the documents is appended hereto.

3. The present application does not meet the requirements of Articles 33(1) PCT, because the subject-matter of claim 2 is not novel in the sense of Article 33(2) PCT.

3.1 Claim 2 defines a storing method for amino-acid or nucleic-acid sequence information which is based on the separation of an alignment information into a sequence information and a gap information expressing correspondence between sequences.

Storing methods which separate sequence information from "gap information" as claimed are well known in the prior art.
D1 relates to the EMBL Nucleotide Sequence Database which is maintained and distributed at the European Bioinformatics Institute (EBI).
Database entries are stored in a particular format which inter alia comprises an accession-number being used for identifying the different database entries.
The EMBL Database also permits the insertion of "unfinished" sequences in several phases (HTG PHASES), where sets of sequence pieces are entered, each sequence being indexed and located in terms of its base pair number (see D1, page 20, section "Unfinished HTG data").
This situation is a full anticipation of the features included in claim 2: The sequence information is given in the body of the entry corresponding to the accession number and the feature identifiers in the header of the entry identifying each contiguous sequence piece can be regarded as the gap information expressing the correspondence between sequences in the sense of claim 1.
The correspondence is clearly expressed in terms of the locations in the sequence chain.
Thus, claim 2 is completely anticipated by D1 and therefore lacks novelty.

3.2 It should be noted that for the comparison of paragraph 3.1 above the term "alignment" was interpreted to stand for "the appropriate or expected relationship of one thing to another or others", which certainly encompasses the relationship between two sequences within a larger piece of data, as described in D1.
D1 however does not explicitly describe how sequence data of the EMBL database is **compared** to new DNA data.
However, even a clarification to that end would not render the claim inventive, since it is considered to be perfectly clear to the skilled person that once sequence and gap information is established for the items to be compared, they will certainly be used in the process of finding correspondences between the sequences concerned.
Such a (hypothetical) claim would then lack an inventive step as required by Articles 33(3) PCT.

4. The communication method defined in claim 9 fully corresponds to the storing method of claim 2 and is therefore also anticipated by the disclosure of D1, since the storing process necessarily comprises the communication of the data to the data carrier.

5. As to the determination of a unique identifier of an alignment information, any sequence piece entered as unfinished HTG data in the EMBL Nucleotide Sequence Database is certainly uniquely identifiable through accession number and indication of base sequence range within the record.
Claim 11 is therefore also anticipated by D1.

6. Dependent claims 3-8, 10 and 14-16 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step, the reasons being as follows:

Claims 3-5 and 7,8 and 14-16 only define straightforward implementation details directly derivable from the disclosure of D1;

Claim 6 defines the reference to residue numbers of another sequence for the description of gap information which is not explicitly disclosed in D1. However, as

already set out in paragraph 3.2 above, a skilled person would certainly consider the "exploitation" of the gap information description already known from D1 such that duplication of information storage is avoided. This leads directly to the solution of using residue numbers of another sequence as defined in claim 6. Claim 6 therefore lacks an inventive step (Articles 33(1) and (3) PCT).

Concerning the removal of redundancies of the sequence information prior to communication as defined in claim 10 it should be noted that this feature merely states a principle well known in the field of telecommunications: the efficient use of the bandwidth of any transmission channel can be improved by removing redundancies in the data to be transmitted. The application of this concept to the biotech data is considered to be straightforward.

7. In view of the very pertinent cited prior art, it is not at present apparent which part of the application could serve as a basis for a new, allowable set of claims. Should the applicant nevertheless believe that a specific combination of features, which has not yet been discussed, could be considered inventive, he is invited to specify such a combination in a new set of claims, taking care to overcome the objections raised in paragraphs 3-5 above.
Applicant should also indicate in the letter of reply why such a combination should be considered inventive using **well-founded arguments** making the inventive contribution to the state of the art clear.

Re Item VII
Certain defects in the international application

8. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

9. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

10. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).

Re Item VIII

Certain observations on the international application

11. Claim 9 includes the expression:

"..the communication of the gap information at least out of the informations"

which does not seem to make sense, since it remains unclear how information can be communicated "out of the informations".
Claim 9 therefore violates the provisions of Article 6 PCT.